



## Complete Summary

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### GUIDELINE TITLE

Pharmacists: partners in health care for HIV-infected patients.

### BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Pharmacists: partners in health care for HIV-infected patients. New York (NY): New York State Department of Health; 2006 Jan. 28 p.

### GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

SCOPE  
METHODOLOGY - including Rating Scheme and Cost Analysis  
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT  
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## SCOPE

### DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection

### GUIDELINE CATEGORY

Counseling  
Management

### CLINICAL SPECIALTY

Allergy and Immunology  
Family Practice  
Infectious Diseases  
Internal Medicine  
Pharmacology

## **INTENDED USERS**

Advanced Practice Nurses  
Health Care Providers  
Nurses  
Pharmacists  
Physician Assistants  
Physicians  
Public Health Departments

## **GUIDELINE OBJECTIVE(S)**

To address the role of pharmacists in medical care of human immunodeficiency virus (HIV)-infected patients

## **TARGET POPULATION**

Human immunodeficiency virus (HIV)-infected patients

## **INTERVENTIONS AND PRACTICES CONSIDERED**

1. Patient education about the importance of adherence to medication regimen, side effects of medications, and drug-drug interactions
2. Reviewing prescriptions and preventing medication errors
3. Communicating medication-related problems to the prescribers
4. Helping with pharmacologic and dietary management of antiretroviral (ARV)-related morbidity
5. Providing sources for financial assistance programs
6. Helping in servicing patients pending Medicaid eligibility

## **MAJOR OUTCOMES CONSIDERED**

Patient adherence to antiretroviral medications

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Not stated

### **NUMBER OF SOURCE DOCUMENTS**

Not stated

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Expert Consensus (Committee)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

Not applicable

## **METHODS USED TO ANALYZE THE EVIDENCE**

Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with HIV infection. Committees\* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees\* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

\* Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Committee
- Women's Health Committee
- Substance Use Committee
- Physician's Prevention Advisory Committee
- Pharmacy Committee

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

## **RECOMMENDATIONS**

### **MAJOR RECOMMENDATIONS**

Pharmacists have the opportunity to educate patients about the safe and appropriate use of medications and should provide ongoing education to patients to ensure successful treatment with highly active antiretroviral therapy (HAART).

#### **Confidentiality**

Patient confidentiality should be maintained at all times. A private area designated for patient counseling sessions will foster an environment that encourages an open dialogue between the pharmacist and patient.

All pharmacy staff should be aware of and comply with the Federal Health Insurance Portability and Accountability Act (HIPAA) to ensure patient confidentiality. HIPAA regulations allow information to be exchanged among healthcare providers if it is needed for treatment, payment, or healthcare operations. Further mention of communication between and among pharmacists and other healthcare providers and patients in this document assumes strict compliance with the HIPAA regulations. More information about HIPAA can be found at: [www.health.state.ny.us/nysdoh/hipaa/hipaa.htm](http://www.health.state.ny.us/nysdoh/hipaa/hipaa.htm).

Pharmacists in New York are required to receive training in, and comply with, New York State Public Health Law article 27-F, which also regulates how human immunodeficiency virus (HIV)-related information about testing, counseling, and partner notification may be transmitted. Pharmacists should comply with this law to the fullest extent.

### **Contributions to HIV Management**

#### **Education**

Pharmacists and clinicians should know how to access accurate and updated information. Listed in Appendix A of the original guideline document are some of

the available resources, including guidelines for treating HIV, current clinical trials, drugs that interact with antiretroviral (ARV) agents, metabolic and morphologic complications associated with ARV therapy, and HIV drug resistance.

**Key Point:**

Keeping up-to-date with HIV management and ARVs will help pharmacists provide the best information to HIV-infected patients and help prevent medication errors.

Adequate time is needed to educate the patient about the goals of therapy and the need for strict adherence due to the complexity of HIV disease, the need for long-term potent combination ARV therapy, and the potential for developing ARV resistance. These educational sessions are essential upon initiation of therapy, but should also take place frequently throughout the treatment course.

Various HIV-related patient education aids are available for distribution to patients. Because of the rapid changes that occur with ARV doses and combinations, every attempt should be made to ensure that these patient education tools are updated as necessary. Personalized education materials may be developed where necessary, using language that is easily understood by the patient, culturally sensitive, consistent with the patient's level of education, and free of medical jargon.

*Key Points to Communicate to Patients*

Pharmacists should discuss HIV management with patients, even if it duplicates the prescribers' discussions. Visual aids can be used to demonstrate the relationship between poor medication adherence and ARV resistance to help patients understand the importance of taking their HAART regimens as prescribed. Pharmacists should help patients understand that poor adherence leads to higher viral load, which increases HIV transmission potential.

**Key Point:**

One way to ensure that a patient understands his/her drug regimen is to have the patient repeat back to the pharmacist the instructions for taking medications.

Adherence

Adherence to HAART is one of the most important aspects of HIV care. Pharmacists should counsel patients about the need for strict adherence to their ARV regimen because it is necessary for maintaining treatment benefit and preventing the development of HIV resistance.

**Key Points:**

- Pharmacists should counsel patients receiving ARV therapy about the need for strict adherence and the risk of viral drug resistance when adherence is compromised.
- Pharmacists should assess patient adherence by using finite time intervals when inquiring about the patient's self-reported adherence (i.e., number of

doses taken and missed in the past day and past week). (Refer to Table 1 in the original guideline document for information on advantages and disadvantages of different methods of adherence assessment).

- Pharmacists should offer adherence tools, such as pillboxes, beepers, and reminder phone calls, to all HIV-infected patients receiving highly active (HAART).
- Pharmacists are encouraged to contact prescribers when they identify patients who are non-adherent to HAART.

Patients should be counseled that taking HAART medications <95% of the time can significantly increase their chances of developing resistance.

### Assessing Adherence

Strategies used to assess ARV adherence in the outpatient setting include self-report, pill counts, electronic monitoring, pharmacy refill monitoring, therapeutic drug monitoring, directly observed therapy (DOT), and modified directly observed therapy (MDOT). Although each of these methods has been used, advantages and disadvantages are associated with each approach. Table 1 in the original guideline document lists some of the common advantages and disadvantages of each method of adherence assessment.

### Language and Culture

Attention to language and use of culturally sensitive education materials is essential. Many HIV-infected people living in New York speak English as a second language or do not speak English at all. Pharmacists should make every attempt to communicate with patients in the language that is most comfortable to the patient. Using multilingual staff and providing written materials in the language that is most prevalent in the service population is a welcoming sign and may encourage a more trustworthy atmosphere between pharmacists and patients.

Pharmacists should explain, in a culturally sensitive and nonjudgmental manner, the benefits and risks of not taking medications as prescribed and the possible effects of using other remedies to treat HIV infection.

### Side Effects and Toxicities

The pharmacist should educate the patient about potential drug toxicities, assess for the presence of any adverse effects, and assure the patient that these toxicities are being monitored and addressed by their prescriber. Pharmacists routinely make recommendations regarding management of side effects with over-the-counter and non-drug interventions, such as taking medications with food if the medications irritate an empty stomach or taking drugs that may cause drowsiness at bedtime. In an effort to avoid premature discontinuation of an ARV agent, the patient should be informed that many toxicities subside after a few weeks of initiating therapy. Before discontinuing HAART, the patient should be advised to call his/her prescriber and discuss any adverse effects they are experiencing.

### Review of Medication Profile

At every visit to the pharmacy, the patient's medication profile should be reviewed for new drugs (including over-the-counter medication and herbal/alternative therapies), medication changes, missed refills, and medication-related problems. If the pharmacist has questions about a patient's medication profile that the patient cannot explain, the prescriber should be contacted for clarification.

#### New Prescriptions and Current HAART Regimen

Refer to the original guideline document for the list of essential patient counseling points for all new prescriptions and for questions concerning current HAART regimens.

#### Written Medication Schedule

Some patients may benefit from a written medication schedule tailored to their particular regimen. The pharmacist can help patients determine the most appropriate times to take their medication while considering the patient's daily routines, drug-food interactions, and potential drug-drug absorption related interactions. Stickers with pictures of ARV agents (see Appendix C of the original guideline document) may help patients who have difficulty remembering drug names and distinguishing between drugs to remember to take their medications correctly and on schedule.

#### Refills

Patients should be encouraged to refill all ARV prescriptions at the same time because this has been found to reduce the number of missed doses, thus, improving patient adherence. Patients receiving other medications for comorbidities should be encouraged to have those prescriptions refilled at the same time as the ARV prescriptions. By evaluating patient refill histories, pharmacists may be able to provide an accurate measure of adherence to the prescriber.

Patients may receive new prescriptions at different times of the month. When this occurs, the quantity dispensed on the new prescription should be adjusted so that the new prescription's refill will coincide when other prescriptions are due to be refilled.

#### **Review of Prescriptions and Prevention of Medication Errors**

To ensure accurate dispensing of medications, pharmacists should review any dosage adjustments, formulation changes, and drug substitutions with the patient's prescriber. Medication prescribing errors are likely to occur with HIV medications because of the complex nature of HAART regimens. Types of HIV-specific medication prescribing errors are shown in Table 2 of the original guideline document.

#### **Strategies to Prevent Medication Errors**

Abbreviations can cause unintended consequences or adverse events if misinterpreted. Pharmacists should clarify prescriptions that contain abbreviations

and discourage their use by prescribers. Pharmacists should also encourage prescribers to write both the generic and brand names on HAART prescriptions to minimize errors related to like-sounding medications.

Hospital pharmacists should review each patient's medication record on a regular basis to detect missing, discontinued, or misspelled orders that could result in medication errors. Pharmacists who screen new orders and discharge prescriptions may also identify and prevent potential errors.

### **Key Point:**

Pharmacists can contribute to the optimal care of patients by encouraging patients to fill prescriptions at one pharmacy.

Patients receiving prescriptions from multiple pharmacies may be at increased risk for unrecognized adverse effects, medication errors, and/or drug interactions. Patients should be encouraged to inform pharmacists and prescribers of all the healthcare providers from whom the patient is receiving treatment to ensure ongoing, proper communication that will help to minimize errors.

Pharmacies use a Drug Utilization Review (DUR) program, a software program that evaluates prescription drug use, physician prescribing practices, or patient drug use, to determine the appropriateness of drug therapy. DUR often focuses on patient overutilization. It can assist in reducing dispensing errors and promote patient safety. If a drug alert appears when the pharmacist enters a prescription into the computer, the pharmacist should consult the patient's provider to discuss the alert. Pharmacists should counsel the patient and not override an alert without first consulting the provider.

## **Communicating Medication-Related Problems**

### **Adverse Effects**

HIV-infected patients may see their pharmacists more often than they see their healthcare provider; thus, some patients may initially report problems with side effects to their pharmacists and not to their prescriber. Pharmacists can contact the patient's prescriber when the patient reports difficulties with medication side effects that the patient has not discussed with the prescriber. This provides an opportunity for the prescriber to become aware of the adverse effects and for the pharmacists to advise prescribers on the management of these ill effects.

### **Drug-Drug Interactions**

Drug interactions have become an increasingly complex challenge in the management of HIV-infected patients. Pharmacists are at the forefront for alerting and educating healthcare providers about known adverse interactions. For further information on drug-drug interactions refer to the *HIV Drug-Drug Interactions* chapter in the *Criteria for the Medical Care of Adults with HIV Infection* manual, also available at: [www.hivguidelines.org](http://www.hivguidelines.org).

### **Co-Infections**



Many HIV-infected individuals are co-infected with hepatitis B and C. In patients with chronic hepatitis and significant liver dysfunction, certain medications should be avoided or doses should be adjusted according to the extent of liver damage. Most prescribers will separate combined-dose medications to individual medication doses when the combined dose is contraindicated (e.g., Combivir and Trizivir should not be used in patients with renal insufficiency) the components should be separated and the dose adjusted. However, if an adjustment is not made, the pharmacist should contact the prescriber to discuss alternatives to using combined-dose medications. Pharmacists can educate prescribers about the precautions with medications for co-infections.

### **ARV-Related Morbidity**

Lipodystrophy, metabolic acidosis, new-onset diabetes mellitus, hypertension, and dyslipidemias are common comorbidities that occur with the use of ARV therapy. The development of these complications, especially if patients are not informed in advance, may lead to non-adherence to medication regimens. Pharmacists can contribute to the careful pharmacologic and dietary management that is required for the treatment of multiple diseases and disorders and can work with prescribers on the prevention and management of ARV-related morbidity.

Refer to Table 3 in the original guideline document for information on drugs associated with ARV-related side effects and complications.

Refer to the original guideline document for information on financial assistance for patients with HIV/acquired immunodeficiency syndrome (AIDS).

### **How to Service Patients Pending Medicaid Eligibility to Minimize Pharmacists' Financial Exposure**

- Accept only patients from a dedicated referral source
- Accept only patients working on obtaining Medicaid
- Obtain date patient applied for Medicaid
- When accepting a Medicaid pending patient, know the therapy
- Accept only a pending patient for medication/supplies
- When accepting a pending patient, only dispense (when able) a 2-week supply of medication or supplies at a time

### **CLINICAL ALGORITHM(S)**

An algorithm is provided in the original guideline document: Adherence Algorithm – Monthly Assessment and Plan.

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of evidence supporting the recommendations is not specifically stated.

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Improved role of pharmacists and, as a result, improved medical care of human immunodeficiency virus (HIV)-infected patients

### **POTENTIAL HARMS**

Not stated

## **IMPLEMENTATION OF THE GUIDELINE**

### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with HIV infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

#### **Guidelines Dissemination**

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative, the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the NYSDOH Distribution Center for providers who lack internet access.

#### **Guidelines Implementation**

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the Clinical Education Initiative (CEI) and the AIDS Education and Training Centers (AETC). The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

## **IMPLEMENTATION TOOLS**

Clinical Algorithm  
Personal Digital Assistant (PDA) Downloads

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Living with Illness

### **IOM DOMAIN**

Effectiveness  
Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

### **BIBLIOGRAPHIC SOURCE(S)**

New York State Department of Health. Pharmacists: partners in health care for HIV-infected patients. New York (NY): New York State Department of Health; 2006 Jan. 28 p.

### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

### **DATE RELEASED**

2006 Jan

### **GUIDELINE DEVELOPER(S)**

New York State Department of Health - State/Local Government Agency [U.S.]

**SOURCE(S) OF FUNDING**

New York State Department of Health

**GUIDELINE COMMITTEE**

Not stated

**COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Not stated

**FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

**GUIDELINE STATUS**

This is the current release of the guideline.

**GUIDELINE AVAILABILITY**

Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

**AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Appendix A: educational materials for pharmacists and prescribers. New York (NY): New York State Department of Health; 2006 Jan. Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).
- Appendix B: adherence algorithm: monthly assessment and plan. New York (NY): New York State Department of Health; 2006 Jan. Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).
- Appendix C: antiretroviral agents used in the treatment of HIV infection. New York (NY): New York State Department of Health; 2006 Jan. Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).
- Appendix D: barriers to adherence. New York (NY): New York State Department of Health; 2006 Jan. Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 90 Church Street, 13th Floor, New York, NY 10007-2919

This guideline is available as a Personal Digital Assistant (PDA) download from the [New York State Department of Health AIDS Institute Web site](#).

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## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI Institute on September 12, 2007.

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Date Modified: 9/15/2008

